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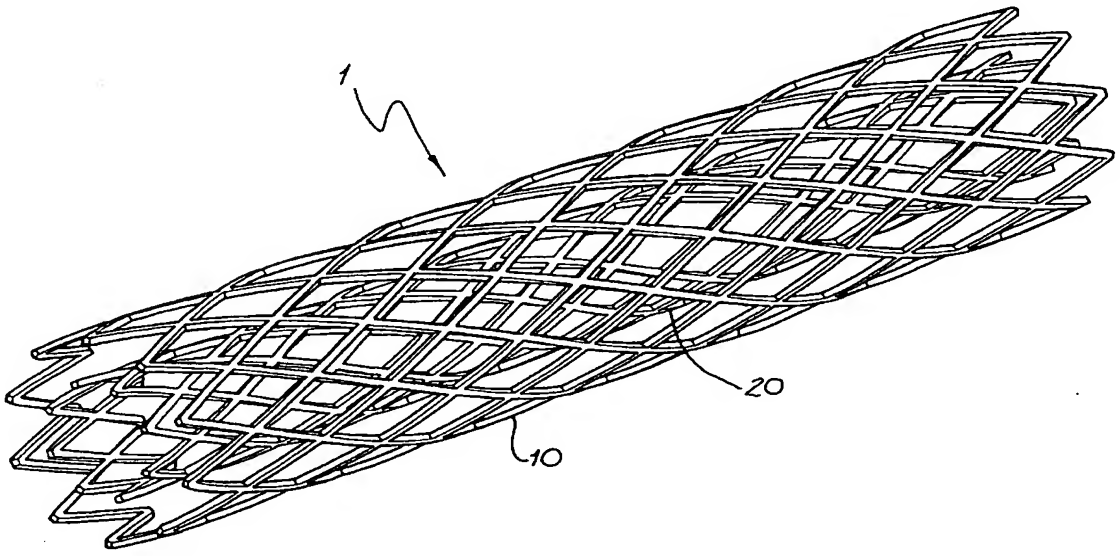
(54) Title: MODULAR STENT SYSTEM AND DELIVERY MEANS



(57) Abstract: An intraluminal stent (1) made up of a first stent member (10) and a second stent member (20) such that the first stent member (10) may be rotated relative to the second stent member (20) to vary the properties of the stent either prior to or during insertion into a vassel of a patient.

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"Modular stent system and delivery means"

Field of the Invention

The present invention relates to a stent for placement in a bodily vessel or cavity and a method of placement of such a stent.

Background of the Invention

Vascular occlusion and occlusion of other vessels is a common form of disease. Such diseases include atherosclerosis which is characterised by an accumulation of plaque from cholesterol residues. The build up of plaque subsequently thickens and hardens the arterial wall to create an arterial stenosis. The resultant narrowing of the artery has adverse effects on blood flow through the vessel.

Current medical practices and techniques employ both invasive and non-invasive procedures to address stenosis of a vessel. One such procedure involves the delivery of an intraluminal stent to the site of a stenotic lesion.

Conventional use of stents has involved inserting a stent percutaneously through a distal and connecting vessel to that in which the stent is to be used. The device can be inserted through the femoral artery in a catheter to the site in which the stent is to be used, for example for treatment of a stenotic lesion within the aorta. The device is then released from the catheter and expanded to the required size, extending above and below the lesion to effectively bridge the lesion.

A procedure termed "balloon angioplasty" can also be used in the treatment of stenotic disease. In this procedure, a deflated balloon is delivered to the site of a stenotic lesion. When in place, the balloon is inflated to break down the stenotic lesion.

Although both of the above procedures are commonly employed, the rate of re-stenosis is unacceptably high in both stent and balloon angioplasty procedures. Approximately 40% of patients treated with balloon angioplasty show restenosis of the vessel, whereas the vessels of patients treated by stent insertion are likely to restenose in 20% of cases.

The present invention is directed at overcoming problems encountered in the prior art.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention consists in an intraluminal stent comprising:

a first stent member comprising an elongate tubular body, said tubular body having a first cell structure; and

a second stent member comprising an elongate tubular body, said tubular body having the same or a different cell structure to the cell structure of the tubular body of the first stent member;

wherein the first stent member and the second stent member are capable of expanding or being expanded from a radially compressed state to a radially expanded state, at least a portion of the second stent member being positionable within the first stent member and wherein further said first stent member and said second stent member are rotatable relative to each other.

In a second aspect, the present invention provides a method of delivering and positioning the stent according to the first aspect of the invention in a vessel of a patient, the method comprising the steps of:

(i) introducing a catheter or other delivery device into a vein, artery or other vessel in the body of a patient when the tubular body of the first and the second stent members are in the radially compressed state;

(ii) causing the first stent member and the second stent member to be carried through the catheter or other delivery device to a target site of stenosis;

(iii) causing or allowing the first stent member to move from its radially compressed state to its radially expanded state;

(iv) causing or allowing the second stent member to move from its radially compressed state to its radially expanded state such that it overlaps with at least a portion of the first stent member; and

(v) withdrawing the catheter or other delivery device along with any other apparatus used to introduce the intraluminal stent into the vessel from the body of the patient.

In a third aspect, the present invention provides a delivery system for the delivery of the intraluminal stent of the first aspect to a target vessel, said delivery system comprising an introducer catheter having an elongate tubular body to allow the passage therethrough of a placement catheter wherein said placement catheter has an elongate body adapted to carry both the first stent member and the second stent member at a position intermediate a proximal and a distal end of the elongate body.

Preferably, the second stent member is rotatable relative to the first stent member when the first stent member is in its radially expanded state and when the second stent member is in its radially compressed state.

Typically, the first stent member and the second stent member are connected to each other via a connecting means. Preferably, the connection is such that it still enables rotation of the second stent member relative to the first stent member, at least when the second stent member is in its radially compressed state. However, when both the first stent member and the second stent member are in their radially expanded states, the first stent member and the second stent member may be connected such that each stent member is prevented from rotating relative to each other.

The first and the second stent members may be of the same length or of differing lengths to each other.

While the tubular body of the first stent member and the tubular body of the second stent member may be formed of a thin biocompatible material such as Nitinol™ or stainless steel, other alloys such as tantalum or Elgiloy are also envisaged. The

tubular body of each stent member may be bare or may be coated with a material having an elastic property such that the coating material is capable of covering the tubular body in both the radially compressed state and the radially expanded state.

In a preferred embodiment of the invention, the tubular body of each stent member may be formed from other suitable biocompatible materials, selected, for best results, on the basis of the material's capacity to withstand the compressive forces of a stenotic lesion and maintain patency of a vessel throughout the life of the stent.

There are at least three preferred mechanisms whereby the tubular body of both stent members may change from the radially compressed state to the radially expanded state. For instance, the tubular body may be expanded by the force of an inflating balloon within the tubular body or by some other mechanically applied force.

Alternatively, the tubular body of either stent member may be made from a shape memory material as mentioned above wherein the patient's body temperature causes the temperature of the tubular body to rise, thereby enabling the tubular body to self-expand and take on its "memorised" shape.

In a further embodiment, the tubular body of either stent member may self expand following deployment of the tubular body from an introducer catheter used to introduce the stent according to the present invention into the body of a patient. This particular embodiment relies upon spring expansion of the material of the tubular body following release of the compressive force of the introducer catheter.

The first stent member and the second stent member may expand by different mechanisms relative to each other. For example, preferably the first stent member is made from a shape memory material as mentioned above wherein the patient's body temperature causes the temperature of the tubular body to rise, thereby enabling the tubular body to self-expand and take on its "memorised" shape.

The second stent member may be of the type which is balloon expandable and, accordingly, may be made from a material such as stainless steel or any other suitable material which is readily radially expanded upon exertion of pressure by a balloon.

Various combinations of the above mechanisms are envisaged, for example, both stent members may be spring expandable or self expandable. Alternatively, both stent members may be balloon expandable. The above examples are in no way limiting to the various possible combinations of mechanisms to cause or allow the first and the second stent members to move from their radially compressed state to their radially expanded state.

As described in the third aspect of the invention, the first and the second stent members are held on a placement catheter which is moved through the introducer catheter.

When the stent of the invention is appropriately positioned, the introducer catheter may be withdrawn. In this embodiment, it is preferred that the first stent member is self expandable and held in the radially compressed state due to the compression of the introducer catheter. Upon release of this compression, the first stent member moves to its radially expanded state within the vessel of the patient.

The second stent member is preferably balloon expandable such that it may be caused to move to its radially expanded state upon expansion of a balloon member on the placement catheter.

To ensure that both the first and the second stent members are appropriately positioned before the introducer catheter is withdrawn, each stent member may have radio-opaque markers incorporated in their structure. Accordingly, in this embodiment, the surgeon would be able to determine the exact positioning of the first and the second stent members within a vessel(s) of the patient before deployment.

The tubular body of the first stent member and the tubular body of the second stent member may have the same cell structure or different cell structures. In this regard, the cell structure may include relatively large cells with large pores. While one stent member may have a tubular wall with such large pores, the other stent member may have a relatively tighter cell structure with each cell having a relatively smaller pore size. The present invention is in no way limited to particular combinations of cell size or configuration. Furthermore, the cell size and configuration of either stent member may vary along the length of each tubular body. For example it may be desirable to provide a region of the tubular body of either stent member which is made

up of a series of cells which have a smaller pore size relative to the remainder of the tubular body. Such a region provides an area of relatively good expansile strength.

When combined, the mechanical properties of the first stent member and the mechanical properties of the second stent member typically determine the overall mechanical properties of the stent of the invention. The first stent member and the second stent member may be rotated with respect to each other either before delivery to the bodily vessel or after delivery to the bodily vessel. The orientation of the cells of stent members relative to each other determines the overall surface area of the intraluminal stent of the invention and the amount of surface contact the stent has with a vessel wall.

Preferably, the first stent member is made from a relatively thin material which has a relatively poor expansile strength. However, it is desirable that the second stent member has a good expansile strength relative to the first stent member. In this embodiment, the first stent member acts more like a sleeve to the second stent member, the latter providing the skeleton of the stent of the invention and which acts to bridge a stenotic plaque and to keep a diseased vessel open. The second stent member may, therefore, assist in maintaining the first stent member in a radially expanded state.

Additionally, it is preferred that the cells of the first stent member have a relatively smaller pore size than the cells of the second stent member. This is desirable when it is considered that the radial expansion of many stents causes disruption of the stenotic plaque it is designed to bridge. Such disruption may result in fragments of the plaque breaking off and being carried downstream whereupon they may lodge in a smaller vessel, occluding said vessel. Such an embolism is prevented by having the first stent member press against the plaque thereby holding the fragments of plaque, which may be dislodged by the radial expansion of the second stent member, against the wall of the vessel.

Either, but preferably the first stent member may be used to deliver a treatment means to a vessel of a patient. Examples of treatment means include drugs and radiation emitting substances. Furthermore, the tubular body of the first stent member may be coated with materials to promote adhesion of cells or cell growth to assist in securing the tubular body in place in a vessel.

The first stent member and the second stent member may be interconnected such that the first stent member and the second stent member are delivered to the treatment site together. Alternatively, the first stent member may be delivered to the treatment site prior to the delivery of the second stent member.

In either case, it is preferred that the first stent member and the second stent member are delivered through the same delivery catheter or other delivery device.

While the second stent member may be packaged substantially internal the first stent member during delivery, it is preferred that the first stent member and the second stent member are longitudinally interconnected such that the first stent member leads the second stent member along the delivery catheter. As the stent of the present invention is typically delivered to small vessels in the body, such longitudinal connection is advantageous as it avoids overlapping of the stent members during delivery. Overlapping increases the bulk of the stent and reduces the likelihood of delivering such a device to the smaller vessels of the body.

In the above aspects an embodiments of the invention, the term "cell size" defines the area of the perforations penetrating the wall of a stent. The degree or density of cells alters the mechanical properties and defines the amount of surface area contact a stent will have with an inner wall of a bodily vessel. The manner in which the cells are configured provides expansibility of the stents, and can allow a stent to be self expandable.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the present invention is now described with reference to the accompanying drawings:

Figure 1 shows an example of a first stent and a second stent;

Figure 2 shows examples of configurations of a first stent member and at least a second stent member;

Figure 3 shows examples of mesh orientation, configuration and cell size;

Figure 4 shows an example of a second stent member internal of a first stent member;

Figure 5 shows an example of the relationship of meshes of a first stent member and a second stent member throughout relative rotation between the first stent member and the second stent member;

Figure 6 shows an example of a stent being delivered to and implanted within a bodily vessel;

Figure 7 shows a further example of a stent system being delivered to and implanted within a bodily vessel by a delivery means; and

Figure 8 is a perspective view of the second stent member when placed internal the first stent member of the invention.

Detailed Description of the Invention

A stent according to the present invention is depicted in Figs 1 and 8 and comprises a first stent member 10 and a second stent member 20. As depicted in Figure 1 first stent member 10 has a cell size 1, and second stent member has a cell size 2.

Figure 2 shows examples of configurations in which the first stent member 10 and the second stent member 20 can be assembled with respect to each other. The second stent 20 can protrude from the lumen of the first stent member 10 at one end, both ends or not protrude at all. There can be more than one second stent member 20. Two second stent members 20 can be located within the lumen of the first stent member 10, or a second stent member 20 can be located within the lumen of another second stent member 20. Again, various configurations and combinations of more than one second stent member 20 are possible.

Depending upon the treatment requirements, different stent member combinations can be used. Different combinations of first stent member 10 and second stent member 20 change the mechanical and flexural properties of the composite stent

system. Stents system of different lengths and diameters can be configured depending upon application requirements.

Figure 3 shows examples of different cell densities and orientations. The geometric and material properties of the stent, including cell size, cell orientation, stent inner and outer diameter, cell wall size and material from which the stent is made of, determine the flexibility, strength and behavioural characteristics of the stent.

Figure 4 shows a second stent member 20 within the lumen of a first stent member 10. The stent member 20 can rotate with respect to stent member 10 prior to it being expanded. The mechanical properties of the stent system are determined by the individual mechanical properties of the first stent member 10 and the second stent member 20.

Figure 5 shows an example of a first stent member 10 having a cell wall 3 and a second stent member having a cell wall 4, throughout stages of rotation with respect to each other. The first stent member cell wall 3 and the second stent member cell wall 4 provide an effective combined cell geometry and size for contact with the inner wall of a bodily vessel. Depending upon the phase of rotation and cell size of the stents, the amount of contact area between the outer surface of the stent members and the internal surface of the bodily vessel can be predetermined. This stent system provides adjustable cell size.

Figure 6 illustrates an example of delivery and deployment of a stent system in a bodily vessel 5. A first stent member 10 and a second stent member 20 are contained within the lumen of a stent system delivery means 30. In this example, the stent system delivery means is a catheter. The first stent 10 and the second stent are in a radially compressed state.

As shown in Figure 6(a), the delivery means 30 containing the first stent member 10 and the second stent member 20, is within a bodily vessel 5. In Figure 6(b), the catheter of the delivery means 30 is partially retracted from the stent system allowing the first stent member 10 and the second stent member 20 to expand so that the outer surface of the first stent member is engaged with the inner wall of the bodily vessel 5.

Figure 6(c) shows the catheter of the delivery means 30 fully retracted from the stent system and the first stent member 10 and the second stent member 20 fully expanded such that the outer surface of the first stent member 10 is engaged with the inner surface of the bodily vessel 5.

Figure 7 shows an example of delivery and deployment of a stent system within a bodily vessel 5. In Figure 7(a), the stent system having a first stent member and a second stent member is delivered by a delivery means 30 to a predetermined site within the lumen of a bodily vessel 5.

The delivery means includes a catheter 31 and an inflatable balloon expansion means 32. The first stent member 10 is self expandable and contained within the lumen of the catheter 31 in a compressed state. The second stent member 20 is balloon expandable.

In Figure 7(a), the stent system is partially deployed. The catheter 31 is retracted and the first stent member 10 allowed to partially expand such that it engages with the inner surface of the bodily vessel 5. As shown in Figure 7(b), the second stent member 20 can be expanded by the inflatable balloon expansion means 32 during the expansion of the first stent member 10 as in this example, or after complete expansion of the first stent member 10.

In Figure 7(c), the catheter 31 is fully retracted such that the outer surface of the first stent member 10 engages with the inner surface of the bodily vessel 5 fully. The second stent member 20 is fully expanded during the retraction of the catheter 31 as in this example, or can be fully expanded after the first stent member 10 has fully expanded and engages with the inner surface of the bodily vessel 5.

Figure 7(d) shows the first stent member 10 engaged with the inner surface of the bodily vessel 5, and the second stent member 20 expanded such that the outer surface of the second stent member 20 is engaged with the inner surface of the first stent member such that the first stent member 10 and the second stent member 20 cannot rotate with respect to each other.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific

embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. An intraluminal stent comprising:

a first stent member comprising an elongate tubular body, said tubular body having a first cell structure; and

a second stent member comprising an elongate tubular body, said tubular body having the same or a different cell structure to the cell structure of the tubular body of the first stent member;

wherein the first stent member and the second stent member are capable of expanding or being expanded from a radially compressed state to a radially expanded state, at least a portion of the second stent member being positionable within the first stent member and wherein further said first stent member and said second stent member are rotatable relative to each other.

2. The intraluminal stent of claim 1 wherein the second stent member is rotatable relative to the first stent member when the first stent member is in its radially expanded state and when the second stent member is in its radially compressed state.

3. The intraluminal stent of claim 1 or claim 2 wherein the first stent member and the second stent member are connected to each other via a connecting means.

4. The intraluminal stent of claim 3 wherein the connection is such that the second stent member is still rotatable relative to the first stent member when the second stent member is in its radially compressed state.

5. The intraluminal stent of claim 3 wherein when both the first stent member and the second stent member are in their radially expanded states, said first stent member and said second stent member are connected such that each stent member is prevented from rotating relative to each other.

6. The intraluminal stent of any one of the preceding claims wherein the tubular body of the first stent member and the tubular body of the second stent member are coated with a material having an elastic property such that the coating material is capable of covering the tubular bodies in both their radially compressed state and their radially expanded state.

7. The intraluminal stent of any one of the preceding claims wherein the first stent member and the second stent member are balloon expandable.

8. The intraluminal stent of any one of claims 1 to 6 wherein the tubular body of either or both stent members is made from a shape memory material to allow the tubular body to self-expand.

9. The intraluminal stent of any one of claims 1 to 6 wherein the tubular body of either or both stent members is spring expandable.

10. The intraluminal stent of any one of the preceding claims wherein the first stent member and the second stent member expand by a different mechanism relative to each other.

11. The intraluminal stent of any one of the preceding claims wherein the second stent member extends through an internal lumen of the first stent member and along a substantial length of the first stent member.

12. The intraluminal stent of any one of the preceding claims wherein the tubular body of the first stent member and the tubular body of the second stent member are defined by sidewalls made up of a series of cells, said cells having relatively large pores therein.

13. The intraluminal stent of claim 12 wherein one stent member includes cells having relatively large pores and wherein the other stent member includes cells having relatively smaller pores.

14. The intraluminal stent of claim 13 wherein the cells of the first stent member have a relatively smaller pore size than the cells of the second stent member.

15. The intraluminal stent of any one of claims 12 to 14 wherein the orientation of the cells of the stent members relative to each other determines the overall surface area of the intraluminal stent and the degree of surface contact the stent has with a vessel wall.

16. The intraluminal stent of any one of the preceding claims wherein the first stent member is made from a relatively thin material which has a relatively poor expansile strength.

17. The intraluminal stent of any one of the preceding claims wherein the second stent member has a good expansile strength relative to the first stent member.

18. The intraluminal stent of any one of the preceding claims including means to deliver a drug or other agent to a target site.

19. The intraluminal stent of claim 18 wherein the tubular body of the first stent member is coated with a material to promote adhesion of cells or cell growth to assist in securing said tubular body in place in a vessel.

20. The intraluminal stent of any one of the preceding claims wherein the first stent member and the second stent member are packaged in a single delivery catheter.

21. The intraluminal stent of claim 20 wherein the second stent member is packaged substantially inside the lumen of the first stent member during delivery within the delivery catheter.

22. The intraluminal stent of claim 20 wherein the first stent member and the second stent member are longitudinally interconnected such that the first stent member leads the second stent member along the delivery catheter during delivery of the intraluminal stent to a target site.

23. A method of delivering and positioning an intraluminal stent in a vessel of a patient, the method comprising the steps of:

(i) introducing a catheter or other delivery device into a vein, artery or other vessel in the body of a patient, said catheter or other delivery device carrying an intraluminal stent comprising a first stent member having an elongate tubular body, said tubular body having a first cell structure; and a second stent member comprising an elongate tubular body having the same or a different cell structure to the cell structure of the tubular body of the first stent member, said first stent member and said second stent member being rotatable relative to each other,

(ii) causing the first stent member and the second stent member to be carried through the catheter or other delivery device to a target site of stenosis;

(iii) causing or allowing the first stent member to move from a radially compressed state to a radially expanded state;

(iv) causing or allowing the second stent member to move from a radially compressed state to a radially expanded state such that it overlaps with at least a portion of the first stent member; and

(v) withdrawing the catheter or other delivery device along with any other apparatus used to introduce the intraluminal stent into the vessel from the body of the patient.

24. A delivery system for the delivery of the intraluminal stent of claim 1 to a target vessel, said delivery system comprising an introducer catheter having an elongate tubular body to allow the passage therethrough of a placement catheter wherein said placement catheter has an elongate body adapted to carry both the first stent member and the second stent member at a position intermediate a proximal and a distal end of the elongate body.

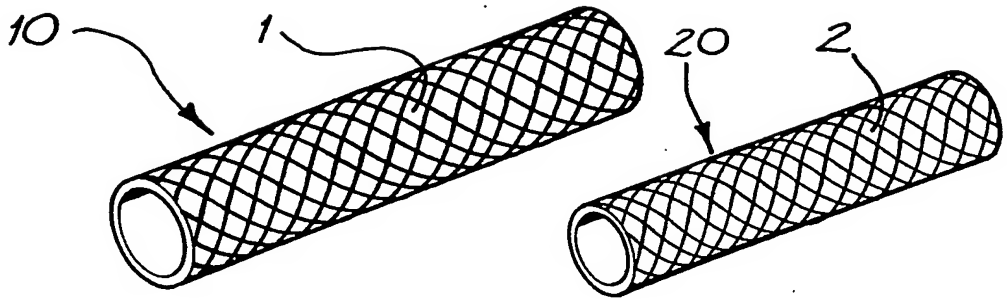

FIG. 1

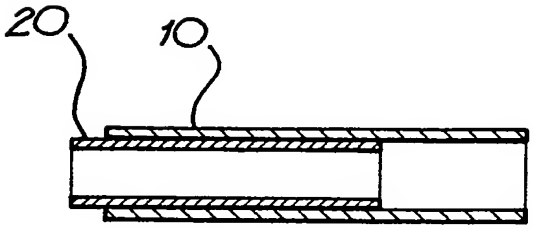

FIG. 2(a)

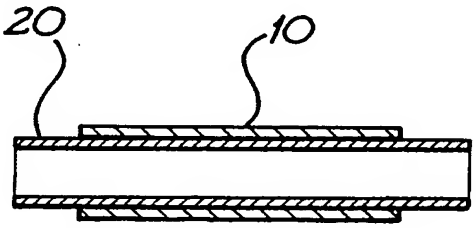

FIG. 2(b)

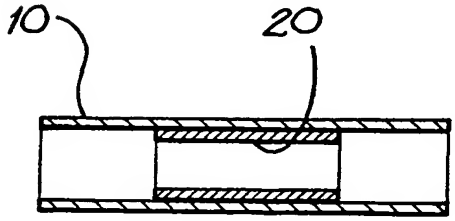

FIG. 2(c)

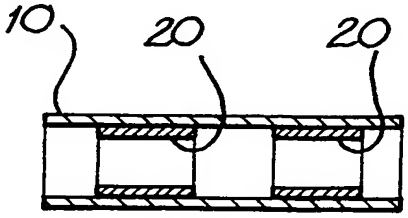

FIG. 2(d)

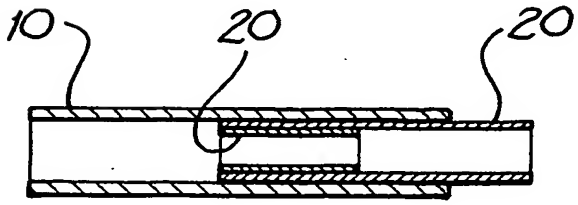

FIG. 2(e)

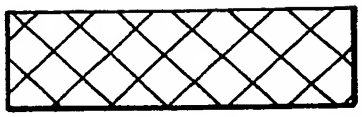

FIG. 3(a)

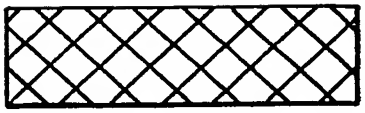

FIG. 3(b)

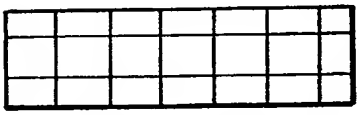

FIG. 3(c)

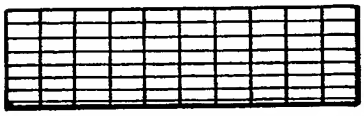

FIG. 3(d)

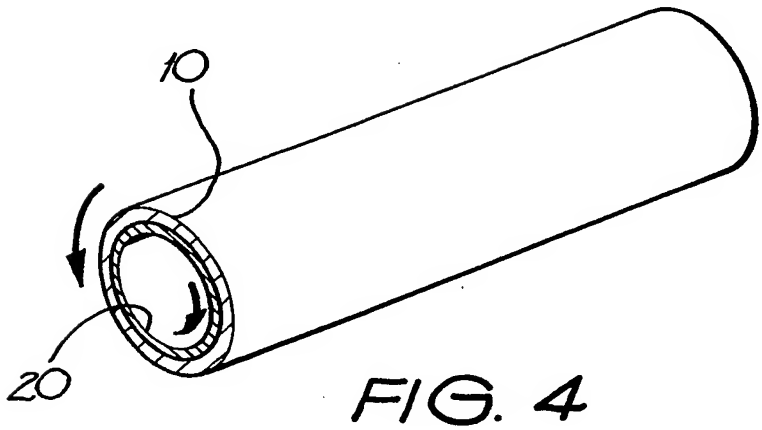

FIG. 4

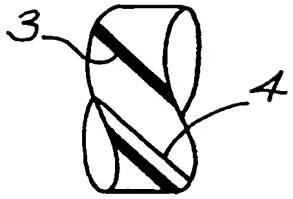

FIG. 5(a)

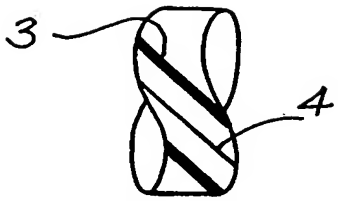

FIG. 5(b)

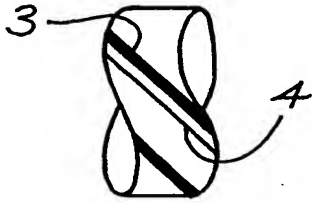

FIG. 5(c)

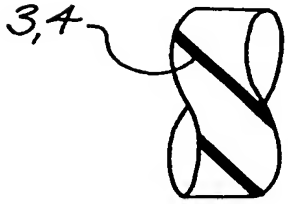

FIG. 5(d)

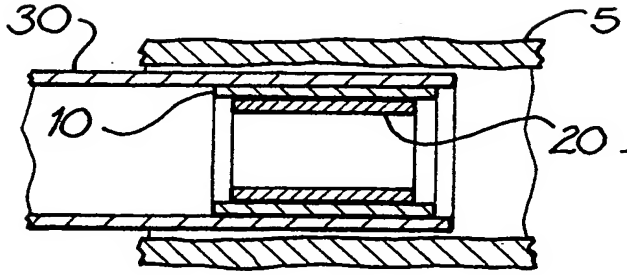

FIG. 6(a)

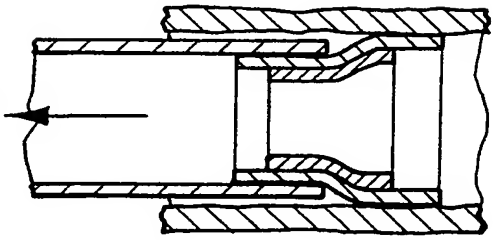

FIG. 6(b)

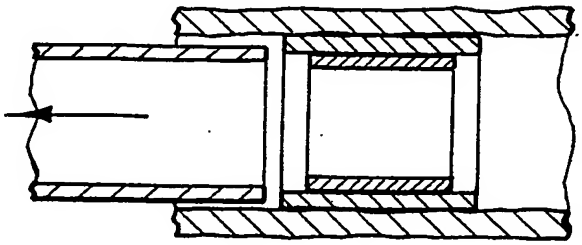

FIG. 6(c)

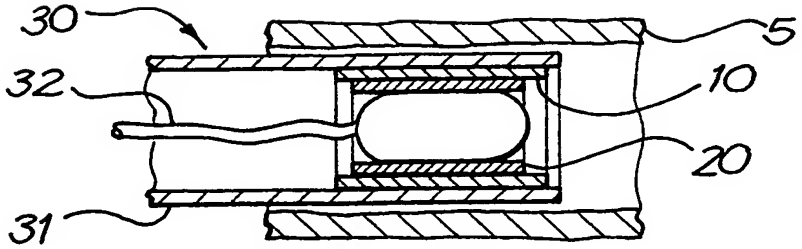

FIG. 7(a)

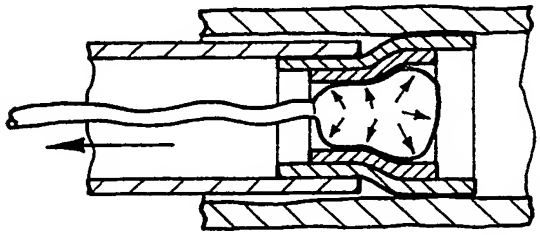

FIG. 7(b)

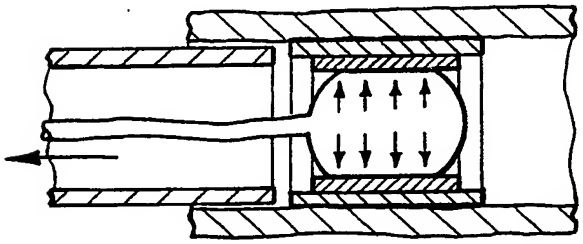

FIG. 7(c)

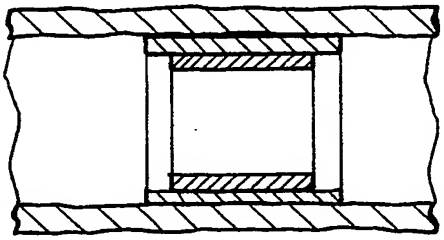

FIG. 7(d)

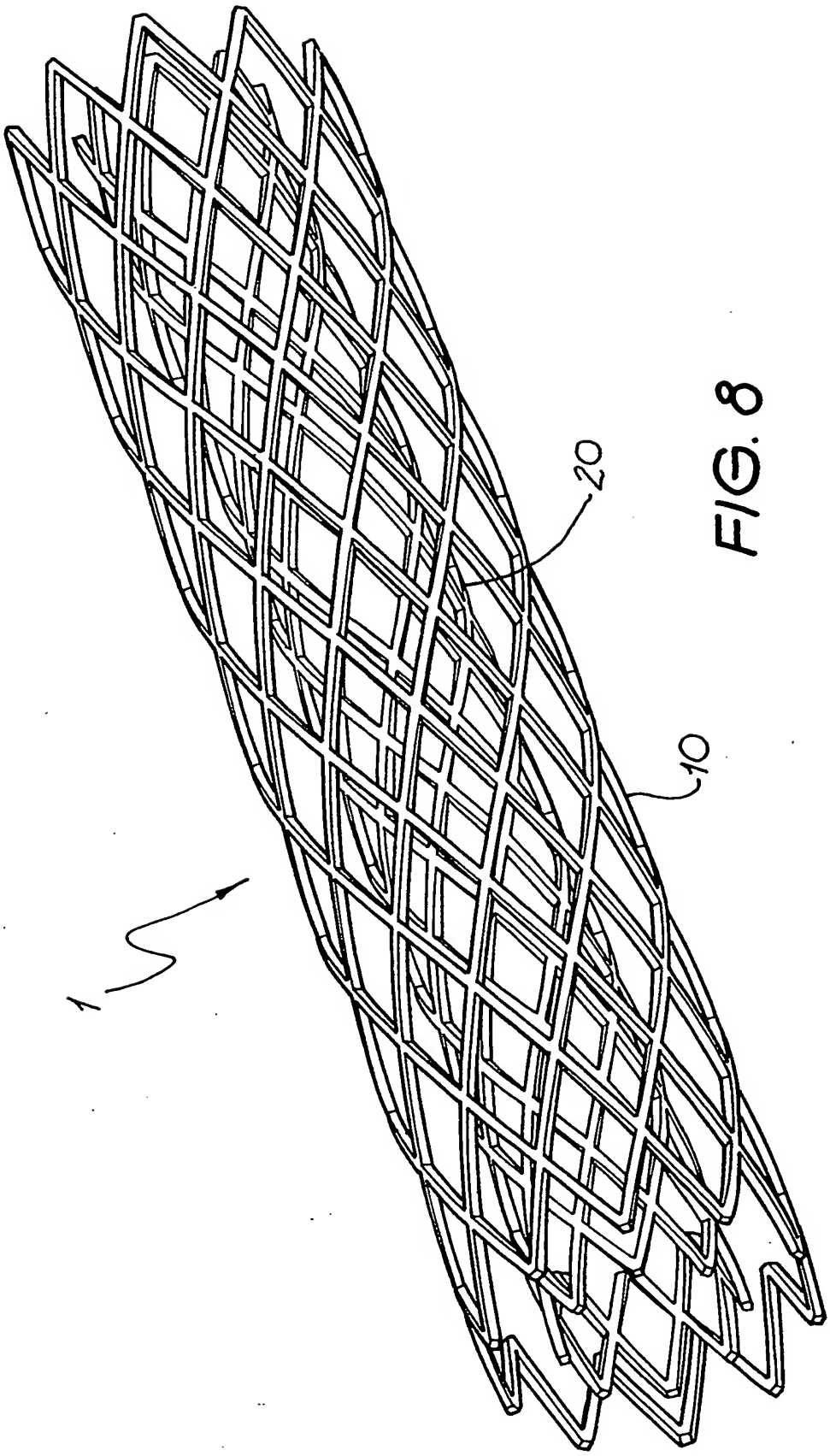

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01153

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61F 2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI Keywords: ipc A61F 2/06, stent, coaxial, telescopic, columinar, rotat+, two, section, segment, inner, outer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5728150 A (McDonald et al) 17 March 1998 See col 3, line 53 - col 8, line 36; col 9, lines 19-59; figures 1, 4	1-9, 11-15, 18-24
X	US 6068655 A (Seguin et al) 30 May 2000 See abstract; col 2, line 18 - col 10, line 21; figure 1	1, 3, 5-9, 12-15, 18-20, 22-24
A	WO 9826731 A2 (Karwoski et al) 25 June 1998 See abstract; page 5, line 12 - page 28, line 35; figures 12A, 12B, 12C, 13A, 13B, 13C	1, 3, 5-9, 11-15, 18-24

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 October 2003	30 OCT 2003
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer JOHN WELSH Telephone No : (02) 6283 2464

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU03/01153

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5728150	AU	40469/97	AU	54520/98	EP	1006941
		US	5676697	US	6090136	US	6120535
		US	6261320	WO	9804212	WO	9822045
US	6068655	AU	31801/97	CA	2257340	EP	0909147
		FR	2749500	WO	9746174		
WO	9826731	AU	23773/00	AU	58984/98	EP	0971643
		EP	1140244	US	5824050	US	5897587
		US	6010529	US	6042666	US	6270523
		US	6287337	US	6315791	US	6416537
		WO	0038754				

END OF ANNEX